

Measuring Costs in Multisite Randomized Controlled Trials Lessons From the VA Cooperative Studies Program

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OBJECTIVES. The interest in the economic impact of new health care interventions has increased dramatically over recent years; however, the results can be highly variable depending upon the economic assumptions made and the approaches taken in collecting the data and in conducting the analyses. This paper describes experiences from the VA Cooperative Studies Program in measuring health care utilization and costs for studies that evaluate clinical interventions.

METHODS. Experiences from two multisite randomized clinical trials (RCTs) are highlighted to

illustrate strategies used to measure costs by directly measuring health care utilization and economic data within the context of the trials.

CONCLUSIONS. Despite the substantial resources required to gather evidence about the cost of care for health care innovations, future VA multisite studies should include accepted health economic approaches to make important contributions to health planning and health policy within and outside the VA health care system.

Key words: costs, health care costs, randomized clinical trials. (Med Care 1999;37:AS27-AS36)

The interest in the economic impact of new health care interventions has increased dramatically in recent years.^{1,2} The demonstration of safety and efficacy alone is no longer sufficient in the complex managed care environment. Paradoxically, whereas managed care systems require cost-effective health care strategies, they are often reluctant to provide resources to obtain the requi-

site data to make such judgements. The resources required to estimate the cost of health care innovations are large, and the results can vary substantially depending upon the assumptions made and the analytic approaches used. Gathering the necessary evidence may increase costs of care in the short run. Those factors led the 1996 US Public Health Service appointed Panel on Cost Effective-

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ness in Health and Medicine (the Panel) to call for a standardized approach to economic analysis in evaluating health and medical innovations. The Panel emphasized the need for stronger methodology to assure that the information in economic analyses is more reliable.³ The Agency for Health Care Policy and Research (AHCPR) has also called for use of cost-effectiveness analysis tools in evaluating health care decisions.² However, even in the "ideal" primary research design, ie, randomized clinical trials (RCTs), cost measurement is not without challenges.⁴

The Department of Veterans Affairs (VA), the largest managed care system in the US, is committed to disseminating cost-effective strategies throughout its facilities nationwide.⁵ Before 1990, the Cooperative Studies Program (CSP) had mainly performed trials designed to assess the efficacy and the safety of therapeutic interventions. In 1990 the VA built upon its successful CSP to establish multisite trials in health services research. Economic analysis has been a major objective of all multisite studies in health services research and in an increasing number of multisite biomedical studies. That experience has led us to develop special methods in economic analysis using VA and non-VA databases.

This paper describes experiences from the Hines VA CSP Coordinating Center in measuring health care costs for multisite studies. First is an overview of general economic research issues which is pertinent to all studies. Next we present experiences from two multisite RCTs to illustrate cost measurement strategies. The examples were selected to demonstrate the challenges of attributing value or cost to the resources used. For each study we present a brief overview, a summary of key results, the economic perspective, the methods used to estimate health care utilization and costs, and the economic outcome measures. Following a description of those two studies, we conclude with a summary of the lessons learned and recommendations for future research.

Economic Analysis Issues in RCTs

Perspective and Objectives. Costs associated with specific interventions may be considered from the perspective of the patient (eg, lost work time, travel, and health insurance co-payments); employer (lost employee productivity and increased insurance premiums); insurance company

(payments for visits, tests, hospital stays, and pharmaceuticals); provider (cost of providing care and cost versus reimbursement for services); or society (opportunity costs and shifts from one segment of society to another). The societal perspective is generally used because it allows evaluation of explicit tradeoffs among competing interests.³

The objective of cost analysis depends upon how costs are presumed to relate to the clinical outcome measure. Cost minimization is appropriate when a clinical treatment is known or is presumed to be as effective as the comparison treatment and the focus is on comparing the relative costs. Cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA) are used when there is uncertainty about the clinical advantage of an intervention relative to its economic impacts. CEA and CBA focus on the marginal costs of an intervention relative to its marginal effectiveness or utility.

Types of Costs Included in the Analyses.

Costs associated with a treatment or intervention fall into two main categories (Gold et al, 1996; p. 178): direct costs and productivity costs. Direct costs include health care (eg, drugs, tests, supplies, health care, and personnel and medical facilities), and nonhealth care (eg, transportation to and from the clinic or the time family members or volunteers spend to provide home care) costs that are consumed in the provision of a health care intervention. Few cost analyses include indirect nonhealth care costs because the data are difficult to quantify and, thus, are often not collected. The omission of those costs may lead to significant biases in results, unless there is strong a priori evidence that those costs are not likely to differ across arms of the study.

Productivity costs are not directly attributable to the treatment but may be the result of the condition or of the treatment. They fall into two main categories. Morbidity costs are those associated with lost or impaired ability to work or to engage in leisure activities caused by illness. Mortality costs are those associated with lost or impaired ability to work or to engage in leisure activities caused by death.

Data Collection Strategies. The Panel advocates the approach or combination of approaches which most "cost effectively" provide sufficient, accurate, and unbiased data.³ Use of both primary and secondary data collection approaches is recommended. However, we caution that primary

data from patient self-reports, or diaries, should be verified with identified providers because patient recall is relatively stable only for periods up to 3 months.^{6,7}

Attributing Value to Health Care Use. From the societal perspective, it is desirable to estimate the real cost by identifying “opportunity costs” or the value of the resources in their next best alternative. Whereas market prices are presumed to reflect opportunity costs, true prices are more difficult to calculate in the health care market and may be subject to market distortions (such as insurance) and financing mechanisms.⁸ In non-priced settings such as the VA, attributing value to specific types of health care use is challenging.^{9,10} Previous efforts have utilized VA’s budgeting system, the Cost Distribution Report (CDR), and expenditure data to approximate costs for VA health care services. Those approaches can be unreliable at the patient level, however.¹⁰

The next section describes the manner in which we dealt with those economic issues in two separate RCTs coordinated at the Hines CSP Coordinating Center.

CSP #8: Does Increased Access to Primary Care Reduce Hospital Readmissions?

Overview

This multicenter RCT was conducted at nine geographically and academically diverse VA Medical Centers to ascertain whether enhanced access to a primary care intervention reduced hospital use among chronically ill veterans over a 6 month period.¹¹ Eligible patients with a diagnosis of diabetes mellitus, chronic obstructive pulmonary disease, or congestive heart failure, either at or before the time of their index admission, were enrolled during an admission to the General Medicine Service.

Following enrollment, 1,396 eligible patients were randomized to receive their usual care or intervention. The intervention, delivered by a registered nurse and primary care physicians, contained an inpatient and outpatient component. The inpatient component included discharge planning with the nurse and physician and the scheduling of a visit within 7 days to that primary care physician and nurse. The outpatient component comprised follow-up telephone contact by

the nurse, a post-charge outpatient appointment within a week after discharge, and a monitoring of the treatment plan by the nurse and physician. Patients were followed for six months and utilization data were tracked for 1 year after randomization. During the study period, 106 patients died and 16 withdrew their consent to be studied; there were no significant differences in the follow up status of patients between the study groups. The primary outcome was the 6-month readmission rate. The main findings from that study were contrary to the study hypothesis; patients receiving the primary care intervention had significantly higher use of inpatient services, however they were more satisfied with their care as compared with the control group.¹¹

Economic Perspective and Objectives

The economic evaluation for this study used a societal perspective which focused on the direct health care costs incurred. We hypothesized that health care costs associated with the intervention would be offset by reduced hospital readmissions (and inpatient costs) during the study period. Thus, we sought to measure and compare costs between the treatment groups. The primary economic outcomes in this study included the cost of hospital readmissions and outpatient care services.

Data Collection Strategy

Data for all VA inpatient care were collected from the Patient Treatment File (PTF). The PTF is a nationwide discharge data set that contains a record for each episode of inpatient care provided in VA hospitals, nursing homes, and domiciliarys.¹² Each record contains data on admission diagnosis, specific bed section of the hospital stay, length of stay, procedures, and discharge information.

Data for inpatient care at non-VA facilities were obtained using Health Care Financing Administration (HCFA) Medicare claims data and patient self report. To validate patient self report, we requested uniform billing forms (UB-82) from hospital providers identified by patients. At the time of patient enrollment, patients gave consent to request their Medicare claims data and to contact their non-VA providers of care. Patient-specific claims data from the Medicare Standard

Analytic Files for all enrolled subjects were requested annually from the HCFA. For each non-VA provider indicated by patient self report, the study coordinator requested a UB-82 to verify patients' service use. Data from the UB-82 forms were abstracted and specific cost categories were totaled. Only non-VA use that was confirmed by UB-82 or HCFA claims was included in the analyses.

Outpatient care included clinic visits, laboratory tests, pharmacy fills, radiology, and nuclear medicine tests. Data for VA outpatient clinic visits were obtained from the national Outpatient Clinic (OPC) files.¹³ Data for all other VA outpatient services were electronically captured from each of the nine study sites' local Decentralized Hospital Computer Program (DHCP) System (now known as Veterans Integrated Services and Technology and Architecture).¹⁴ Working closely with the Information Resource Management (IRM) service at each VAMC site, we developed computer programs to interface with the local DHCP systems for transfer to a centralized site. To avoid losing data because of routine archiving of the DHCP data at sites, the local DHCP data were obtained monthly via computer downloads for all patients enrolled in the study. Data for non-VA outpatient care were obtained through Medicare Outpatient and Part B claims data.

Attributing Value to Health Care Use

As patients were not restricted to use only VA health care, one challenge was to establish a method for valuing resource use that would reflect the differences in the site and intensity of care. Moreover, from the societal perspective, the main interest was on all direct health care costs that would reflect national trends as opposed to local variation. So, when possible we used data that reflected national average costs for hospital, outpatient, and pharmacy service use, as described in the following sections.

Hospital Costs

The study used a resource input analysis approach,⁹ using cost information from the CDR to attribute an average cost to inpatient stays by specific bed sections and outpatient visits. Whereas not a cost-accounting system, the CDR

provides estimates based on annual budgets for each cost center.¹⁰ The cost information from the CDR was used to attribute value to inpatient stays as follows. For each admission the average bed section specific per diem cost was attributed for the length of stay in the specific bed section. The cost for a bed section includes direct and indirect costs of care. Also, given the additional resources associated with open-heart procedures, an additional cost was included for using the open-heart unit and the operating room (OR). For example, a patient with 3 days in an intensive care unit (ICU) and 3 days in the surgery bed section without any surgical procedure had a lower total cost than did a patient with the same length of stay, but with an open heart procedure. Those components were summed to calculate a total cost for all VA-inpatient care for each patient.

For non-VA inpatient care, hospital charge data summarized from the UB-82 were used. Room and board charges were itemized separately from laboratory and procedures. To obtain total charge for an admission, those components from the hospital bill were summed. Cost data were not available from the individual providers, and, therefore, we could not calculate costs from charges.

Outpatient Care

The CDR was also used to estimate costs for VA-outpatient visits. Specific clinic stops were linked with specific cost centers, after which a total cost for each patient was calculated. For laboratory procedures, information from a micro-costing analysis, conducted at the Durham VAMC, was used to attribute value to categories of laboratory tests. Information from the workload reports was used to calculate the cost for four categories of laboratory testing: chemistry/urinalysis (mean of \$1.34 per test); hematology/blood bank (mean of \$5.94 per test); immunology/microbiology (mean of \$26.50 per test); and histology (mean of \$104 per test). That level of detail allowed for the valuation of different categories of tests separately rather than by using an overall average for all laboratory tests from the CDR. The values calculated from this micro-costing analysis were used for all lab tests at all of the sites. A total cost for all VA-outpatient laboratory testing for each patient was calculated.

For all other outpatient care provided by non-VA providers, Medicare fee schedules were

used to attribute value to each service type. The calendar year of 1992 fee schedule with adjustments for inflation using the medical care consumer price index (MCCPI) for subsequent years was used. That value was included in the total cost for non-VA outpatient care and VA-outpatient care for each patient.

Pharmacy Costs

A unique feature of conducting cost studies within the VA is the availability of prescriptions data for each patient. Although costs per prescription were included in the DHCP downloads, those local prices were inconsistent within and across sites. Thus, we used price data for prescriptions from VA Pharmacy Benefit Management. In cases for which a unique National Drug Classification (NDC) code could not be identified, the average price for the drug classification was used. For each patient a total cost for prescriptions was calculated.

Cost Results

Results for selected economic outcomes are presented in Table 1. VA hospital and outpatient visit costs were significantly greater in the intervention group. Non-VA hospital charges were similar for the intervention and control group. Non-VA outpatient charges for the control group were significantly greater than for the intervention group. Additional detail about radiology, nuclear medicine, laboratory and microbiology tests, and pharmacy use is forthcoming.

Strengths and Limitations

The data collection and cost attribution approach used in this multisite RCT had several advantages. First, by making use of existing VA data systems, ie, PTF and DHCP, the study had detailed information about the use of health care at multiple sites. That level of detail allowed for greater flexibility when determining the manner in which to attribute value to the specific services used. As Chapko et al⁹ have pointed out, that flexibility is especially important when studying nonpriced settings as in VA. Second, although non-VA use was low (non-VA outpatient use was 8%; non-VA inpatient use was 5%), we validated data on

non-VA use, which provided a more accurate estimate of costs. Third, the CDR represented a cost attribution method that most closely reflected the costs of VA care. That approach allowed for variation in the use of resources depending upon the specific bed section in which a patient was hospitalized or the specific outpatient clinic setting in which a patient returned for a visit. Fourth, the study was able to account for some additional resources used by patients who had a surgery during their admission by estimating the additional costs caused by specific procedures. Fifth, we were able to capture, with great detail, the level of resources used in the outpatient setting, including pharmacy data. Sixth, by using a uniform approach across all VA sites of care for estimating costs, the study was able to compare cases across sites without biasing the methods in favor of either the treatment or the control group. Finally, by using information from the VA PTF and local DHCP for obtaining resource use data, we were able to link resource use with costs in the CDR.

The data collection strategy and the cost attribution methods used for this multisite RCT also had some limitations. The primary disadvantage of using CDR data is that the intensity of a service is not taken into account in the average cost. Some studies have overcome this limitation by weighting the average cost by another relevant factor, such as the number of physician visits or the amount of nursing care.¹⁵ Instead, we opted to add an additional cost for patients with open-heart procedures. The use of prevailing Medicare rates for procedures, of course, does not reflect the intensity of service required to actually provide the procedure in any specific setting. However, that approach allowed us to account for specific procedure use when the CDR could not.

Another limitation was the use of multiple sources of cost and charge data. Using estimates of VA costs from the CDR, non-VA charges for non-Medicare hospital admissions, and Medicare reimbursement rates for Medicare reimbursed hospital admissions would seem to overweigh the cost of non-VA hospital care. From the perspective of the VA health care system, that overweighing of non-VA care may more accurately reflect the price of "out-of-system" use to VA. However, it might have been better to have been more consistent in valuing health care use using the same metric, ie, costs as opposed to charges. However, we did not have access to hospital-specific costs or the ratio of costs to charges (RCCs).

TABLE 1. Evaluation of a Primary Care Intervention to Reduce Hospital Readmissions (CSP #8): Health Care Use and Costs During Six Month Intervention

Type of Health Care Use	Intervention Group (n = 695)	Control Group (n = 701)	P Value
Inpatient care (mean ± s.d.)			
Number of VA hospital readmissions	0.81 ± 1.1	0.62 ± 0.9	0.005
Number of VA hospital readmission days	7.5 ± 16.0	5.7 ± 12.4	0.025
Number of non-VA hospital readmissions	0.07 ± 0.38	0.09 ± 0.53	0.63
Number of non-VA hospital readmission days	0.48 ± 2.9	0.62 ± 4.0	0.64
Outpatient care (means ± s.d.)			
Number of VA outpatient visits	16.5 ± 13.1	14.9 ± 20.0	0.0001
Number of non-VA outpatient visits	0.19 ± 1.0	0.41 ± 2.0	0.03
Costs (mean ± s.d.), [value range]			
VA hospital day costs	5,438 ± 12,356 [0-148,017]	4,079 ± 9,108 [0-66,788]	0.02
Non-VA hospital day charges	953 ± 5782 [0-75,677]	1239 ± 8500 [0-166,608]	0.64
VA outpatient visit costs	1,036 ± 832 [0-5,221]	927 ± 1,269 [0-16,706]	0.0001
Non-VA outpatient visit charges	97 ± 570 [0-6,753]	194 ± 1,358 [0-27,664]	0.03

CSP#246: Comparing Transurethral Surgery With Watchful Waiting Management for Patients With Moderate Symptoms of Benign Prostatic Hyperplasia

Overview

The main objective of this multisite RCT was to compare the effectiveness of transurethral resection of the prostate (TURP) to watchful waiting (WW) in elderly men with moderate symptoms of benign prostatic hyperplasia (BPH).¹⁶ The RCT randomized 547 men at nine VAMCs to TURP or WW between 1986 and 1989. Patients were each followed for 3 years. The primary outcome was treatment failure, which is defined as the occurrence of any of the following: death, repeated or intractable urinary retention, a residual urinary volume over 350ml, the development of bladder calculus, new and persistent incontinence, a high symptom score or a doubling of the serum creatinine concentration.

Although WW was an acceptable alternative for many patients, surgery was the more effective option on average and did not cause impotence or incontinence. TURP improved urinary symptoms

and substantially reduced risks for acute urinary retention and very high residual urine volume. Surgery also reduced the degree to which patients were bothered by their symptoms and improved activities of daily living.¹⁶ The outcomes of TURP were best for those who were most bothered by their symptoms at baseline.

Economic Perspective and Objectives

This study also used a societal perspective, which focused on the direct disease-specific health care costs incurred. Direct costs were thought to be of prime concern to the VA and to society as a whole. Also, indirect costs were felt to be difficult to quantify and inordinately burdensome to collect. Finally, it was felt that some of the indirect costs of pain and suffering which were most closely related to the treatment alternatives were reflected in the outcome measures, such as the recurrence of complications. The primary economic outcomes in this study included the cost of inpatient care, outpatient care, and pharmaceuticals. Both VA and non-VA health care use were relevant, as the main objective was to evaluate the costs of treating BPH.

TABLE 2. Transurethral Surgery Compared to Watchful Waiting for Moderately Symptomatic Benign Prostatic Hyperplasia (CSP #246): Health Care Use and Costs During Three Years of Follow-Up

Type of Health Care Use	TURP		WW		P Value
	n	%	n	%	
Number of hospitalizations					
0	28	10	106	39	
1	107	39	83	30	
2 or more	139	50	84	30	0.001
Number of GU-related hospitalizations					
0	45	16	189	69	
1	176	64	61	22	
2 or more	55	19	23	9	0.001
Length of stay per hospitalization (mean days ± SD)	7.7 ± 10.1		7.1 ± 11.0		0.002
Length of stay per GU-related hospitalization (mean days ± SD)	6.8 ± 6.5		5.7 ± 3.6		0.04
Number of outpatient visits (mean ± SD)	39.3 ± 85.1		32.5 ± 34.1		0.39
Number of prescription fills (mean ± SD)	54.1 ± 60.5		58.0 ± 56.1		0.13
Costs					
Median total costs [25 percentile-75th percentile]	\$9,184 [6,044-15,967]		\$6,166 [3,134-11,630]		0.0001

The cost effectiveness of TURP versus WW is the focus of continued and ongoing analysis.

Data Collection Methods

VA and non-VA health care use was recorded for each patient. Data were collected for 3 years after randomization. VA utilization data were obtained by review of the patients’ medical records by research assistants at each site, health care use diaries completed by patients, and bimonthly telephone interviews to verify VA utilization and to assess non-VA utilization. Health care use was summarized into one of three categories, as follows:

- 1. Inpatient care, including physician, inpatient hospital, and extended care services.
- 2. Ambulatory care, including physician services, outpatient surgery, lab tests, x-rays, therapeutic procedures, and diagnostic procedures.
- 3. Prescription medications.

Attributing Value to Health Care Use

The attribution methods used placed greater emphasis on capturing key elements of disease treatment rather than on distinguishing variations in the site of care for the treatment. The study used

proxy charges from outside the VA to generate dollar estimates of health care services used.

Inpatient service costs were determined by assigning a Diagnostic Related Group (DRG) for each admission. Using Medicare Part A data the median DRG-specific charge and median professional service fee from the Medicare 5% national sample (1991) were assigned. Each hospitalization and associated costs were classified as being related or not related to the patient’s genitourinary problems as based on the DRG for the admission. The cost of GU-related and non-GU-related inpatient care for each patient was calculated.

To attribute value for ambulatory services, CPT codes were linked to median Medicare Part B reimbursement. The cost for all ambulatory care services was calculated. For outpatient medication costs, the discounted unit cost for the VA was used (1991).

Cost Results

Results for selected economic outcomes are presented in Table 2. The number of hospitalizations, the number of GU-related hospitalizations, and the corresponding hospital length of stay was greater in the TURP group compared to the WW group. The median total cost for TURP patients was \$9,184 compared with \$6,166 for WW (*P* = 0.0001).

TABLE 3. Comparison of Approaches Used in Multisite Studies to Measure Costs

Study Features	Comparing Transurethral Surgery With Watchful Waiting Management for Patients With Moderate Symptoms of Benign Prostatic Hyperplasia (CSP #246)	Evaluation of a Primary Care Intervention to Reduce Hospital Readmission (CSP #8)
Main economic outcome measure	Total direct health care costs for GU-related and all health care use	Total direct health care costs for all health care use
Perspective of analysis	Societal	Societal
Types of health care use collected	Inpatient care (physician services, hospital, and extended care services) Outpatient care (MD services, outpatient surgery, lab tests, x-rays, therapeutic procedures, and diagnostic procedures) Prescriptions	Inpatient care (physician services, hospital, open heart procedures, and operating room procedures) Outpatient care (MD services, office visits, lab tests, radiology procedures) Prescriptions
Data collection method	VA: Medical record review by site coordinators and bimonthly follow-up for verification Non-VA: Patient diaries and bimonthly phone call	VA: PTF, OPC, DHCP computer downloads to a central study coordinator Non-VA: Validated self report, billing data from providers, HCFA claims files (standard analytic files)
Cost attribution methods used	Inpatient: Medicare DRG specific charge, median professional service fee from Medicare 5% sample Outpatient: CPT code linked to median Medicare Part B reimbursement rate Prescriptions: VA discounted unit costs	VA inpatient care: bedsection/cost center-specific average costs from VA CDR Non-VA inpatient care: UB82 hospital charge data Medicare DRG specific charge, charges for physician services VA outpatient care: VA CDR, HCFA CPT code linked RVUs for radiology procedures, workload estimates for laboratory tests. Non-VA outpatient care: Medicare Part B charges Prescriptions: VA unit costs from pharmacy benefits management

Strengths and Limitations

The data collection approaches and cost attribution methods used in this study also had several advantages. First, collecting inpatient and ambulatory care data using the patient medical record was accurate and complete. However, supplementing medical record review with patient self report proved essential: over 12,800 outpatient visits or 66% of all outpatient visits and over 2,900 medications or 56% of all medications were not reported in the patient diaries.¹⁷ Second, the study took non-VA utilization into account and collected

data through patient calendar diaries verified with telephone interviews. However, that data collection effort was large, given the amount of out-of-system utilization that was reported by the study subjects over the 3-year follow up. Overall, only 9.1% of hospital stays, 8.7% of outpatient visits, and 2.9% of prescriptions were non-VA. It is possible that those rates may have been low, at least, partially caused by the intervention itself. Another strength of the study was the use of Medicare reimbursement rates for all inpatient and ambulatory care; it minimized the analysts' time needed for linking files and allowed for valuation using a common metric across sites of care.

There were also limitations in the methods used. Using medical record data to document health care use was expensive, and that expense, when associated with locating and abstracting patient records, may be overwhelming if a patient is treated in multiple settings. As VA develops online databases, more efficient data abstraction strategies may be possible. Second, the efficiency gained by using the common metric across sites of care sacrificed site variations in resource use and costs. That tradeoff was the price of parsimony. But this approach was also consistent with a focus on comparing the overall cost of BPH treatment for WW and TURP patients, and there was no evidence that this strategy biased the results in favor of one treatment arm over the other.

Lessons Learned

The two multisite studies described here, although different in their scope and focus (Table 3), highlight some key lessons in planning new multisite RCTs in VA. First, it is essential to build in some redundancy into collecting data on health care utilization. Patient self-report requires validation against the source of care; thus, diaries are unlikely to be helpful because patients frequently omit utilization.

Second, the cost attribution methods selected should be consistent with the goals of the investigation. The studies described here used very different approaches to attribute value to the health care resources itemized. CSP #8 used multiple levels of data and used cost attribution methods that would maximize the detail of resource use, as follows: resource input analysis was used to value laboratory services, CDR information was used to value VA inpatient and outpatient services with the additional valuation of specific procedures; and proxy values from HCFA were used to value non-VA resource use. Those strategies required a great deal of effort on the part of the analyst to link multiple level files, despite the fact that administrative data were used. As further analysis continues on CSP #8, comparisons between alternative cost attribution methods may provide more lessons. Cost-attribution methods used for CSP #246 comprised the use of HCFA charges for inpatient and outpatient services. That approach had the advantage of being relatively straightforward and consistent across provider site. Billing data from non-VA providers were

necessary and there was no concern about the reliability of the VA CDR. However, that approach had the disadvantage of assuming that reimbursement rates and fees are good indicators of costs.

A third lesson concerns the scope of the economic aspects of the study. The two studies described here focused on direct costs of the intervention under study. In both studies, however, it was felt that the burden of data collection outweighed the potential yield. CSP #246 had a more narrow focus on disease-specific costs, although unrelated direct health care costs were also examined. In both studies it could have been argued that the indirect costs of care were relevant to study; in such a chronically ill population as those studied in CSP#8 it is possible that opportunity costs related to lost work time and/or family burden may have been great and different in the two study arms. In CSP #246 it is also possible that the indirect costs may have differed between the WW and TURP groups. In the future, it will be necessary to measure indirect costs if studies conducted in VA are to be compared with studies conducted outside VA.

Conclusions

The difficulty and expense of measuring health care costs is increasingly more challenging in multisite studies. Strategies for data collection and cost-attribution methods need to be consistent with the study perspective and objectives. Strengths and limitations of data collection methods and cost-attribution methods should be considered to ensure that the study objectives are met. Whereas there are standard cost-analysis methods, as described in the literature, researchers must determine the approaches that are best suited to address their research objectives. For multisite cooperative RCTs, those issues are especially important. Future VA multisite RCTs must also include accepted health economic approaches to ensure that RCTs conducted in VA facilities continue to make important contributions to health planning and health policy within and outside the VA health care system.

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